UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	
	Chapter 11
PURDUE PHARMA L.P., *et al*.,	**Case No. 19-23649 (RDD)**
Debtor.[1]	**(Jointly Administered)**

SEVENTH MONITOR REPORT

Comes now, Stephen C. Bullock, as duly contracted Monitor for Purdue Pharma L.P. to report to the Court as follows:

EXECUTIVE SUMMARY

This Seventh Monitor Report, and the undersigned's third since being appointed on February 18, 2021, will include an outline of actions taken over the last three months to determine compliance with the terms and conditions of the Voluntary Injunction ("Injunction"), discussion of the results of areas of further inquiry or recommendations from the last Report, additional recommendations provided to Purdue Pharma L.P. ("Purdue Pharma" or "the Company"), and the Company's response to those recommendations.

Based on what has been reviewed to date and subject to the recommendations contained herein, Purdue Pharma and the Initial Covered Sackler Persons appear to be making a good faith effort to comply with the terms and conditions of the Injunction, and the Company has been

[1] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF L.P. (0495), SVC Pharma L.P. (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

responsive in fulfilling the Monitor's requests for information, documents, and interviews with Purdue Pharma employees.

INTRODUCTION – STEPS TAKEN SINCE SIXTH REPORT

1. Since the filing of the Sixth Report the undersigned Monitor has continued with a series of interviews with employees at Purdue Pharma, including discussions with the Company's Executive Vice President and General Counsel and Secretary; Vice President, Ethics and Compliance; Vice President, Legal Strategy and Public Health Initiatives; Head of Business Operations; Director, Ethics and Compliance; Associate Director, Ethics and Compliance; Manager, Ethics and Compliance; and Director of Customer Service.

2. Since the filing of the Sixth Report the undersigned Monitor has continued to request, receive, and review a variety of documents, reports, and materials. The undersigned has received information relating to standing requests, new requests, and documents and reports generated by the Company to directly address inquiries made by the undersigned.

SIXTH REPORT RECOMMENDATIONS AND AREAS OF FURTHER INQUIRY

3. In the Sixth Report, eight different recommendations and areas of inquiry were identified. The Company agreed to all recommendations made, and has been assisting in both addressing the recommendations and providing necessary information relating to areas of further inquiry.

4. The recommendations and areas of inquiry included: the Company's Customer Service Department (Paragraphs 9-13); pricing (Paragraph 23); research submitted for publication (paragraphs 86-87); various topic pertaining to Suspicious Order Monitoring, including threshold calculations (Paragraph 152); customer site visits (Paragraph 161); corroboration of pended order justifications (Paragraph 168); further evaluation and assessment

of the system for identifying downstream customer's orders of interest (Paragraphs 180-181); and reporting of downstream customers' orders of interest to their distributor and the Drug Enforcement Administration ("DEA") (Paragraphs 194-195).

5. The recommendations and inquiries, as well as actions taken in response, will be further discussed in each of the sections below.

6. Additionally, where new areas of inquiry have been undertaken since the Sixth Report, these new areas will be discussed.

DISCUSSION AND ANALYSIS

I. BAN ON PROMOTION AND FINANCIAL REWARDS BASED ON VOLUME OF OPIOID SALES

A. Medical Information Team

7. The undersigned has reviewed inquiries made of the Medical Information Team for the period from mid-July to mid-October 2021 and finds the responses and activities of Purdue Pharma's Medical Information team continue to comply with the Injunction.

B. Customer Service Department

8. Prior to filing the Sixth Report, the undersigned Monitor received a letter from the Company's Executive Vice President and General Counsel and Secretary, notifying the undersigned that "Purdue's Law Department became aware that the Customer Service Department, which is part of the Commercial group, may have attempted to resolve certain opioid product complaint issues directly with pharmacies." (Sixth Report, Appendix A.)

9. The undersigned has reviewed the Customer Service call logs reflecting opioid-related calls since November 1, 2019; call logs from the Product Monitoring and the Drug Safety and Pharmacovigilance Departments reflecting opioid-related calls from August 1 to October 21,

2021; call logs from the Medical Information Department from April 9 to October 14, 2021; the Customer Service Product Inquiry Response Policy that had been in effect since January 2020; the Customer Service Standard Operating Procedure effective in July 2021; other non-privileged emails and documents provided in response to information requests from the undersigned; and factual, non-privileged information summaries by the Company's outside counsel, retained at the Company's request to perform a review of the issue.

10. The undersigned also interviewed the Company's Director of Customer Service; Vice President, Ethics and Compliance; Director, Ethics and Compliance; and the Company's outside counsel who conducted the review.

11. The Customer Service Department is part of the Company's Commercial Division, and reports to the Head of Pricing. Prior to approximately two and one-half years ago, the Customer Service Department was part of the Finance Department.

12. The Director of the Customer Service Department has held this position within the Company for over 20 years. In addition to managing the Customer Service Department, the Director coordinates recall procedures following decisions by Regulatory Affairs, is involved with every product launch or extension, and has been involved in orchestrating product donations. The Director is also responsible for price increase notifications, and works closely with the manufacturing and distribution teams when there are supply chain issues and a need to allocate product among customers.

13. In addition to the Director, the Customer Service Department has four representatives who take calls, either transferred from other departments or by a toll-free number, and by email. The inquiries are primarily from patients, caregivers, distributors, and

Health Care Providers, including pharmacies. Those four employees have each been with the Company between seven and 10 years.

14. Only about 25 percent of the Customer Service Department's daily duties entail responding to calls and emails. The Department takes all orders and processes returns, credits, service fees, charges, and other product-related transactions for and from distributor/customers for: Purdue and Rhodes Pharmaceuticals, both Opioid and Non-Opioid products; Adlon Therapeutics; Avrio Health's over the counter products; Noramco; and transactions relating to the export business.

15. Regarding the calls and emails, Customer Service can either answer the inquiry itself or forward the inquiry to other departments within the Company, including Medical Information, Product Monitoring, Drug Safety and Pharmacovigilance, and Law.

16. The Director of Customer Service stated that there were very few changes to the Department's duties and responsibilities following the entry of the Injunction.

17. In January of 2020, however, the Vice President of Ethics and Compliance instructed the Customer Service Department that it should send calls relating to Opioid Product Savings Cards to Medical Information.

18. Also in January 2020, the Customer Service Department set up specific written policies to follow in response to inquiries about Opioid Products. The policies provided that, subject to certain exceptions, "[a]ny call or Email from a Purdue patient/consumer regarding opioids will be referred to Medical Services."

19. Those exceptions included where the call or email inquired about Patient Assistance Programs, indicated that they didn't have insurance and requested a Savings Card, or

was requesting a Savings Card for Butrans. For each of those exceptions, the Company doesn't offer any programs responsive to these inquiries.

20. As to the protocol when a refund was sought, the policy provided as follows:

> "If the caller/email involves a pharmacy or patient refund request due to a Purdue product issue[:] Ensure a product complaint or adverse event has been reported and then secure a copy of the report. If a report has not been filed, . . . transfer the call or forward the email [to Purdue Product Monitoring, for product complaints, and to the Purdue Drug Safety and Pharmacovigilance, for adverse event inquiries]. Once a report has been filed, process the refund request according to Purdue's Product Refund Policy."

21. There were no written policies in place for replacement of an Opioid Product, nor were there express provisions concerning if the call came from a Health Care Provider, rather than a patient. The policy did provide, however, that all product complaint calls and emails should be forwarded to Product Monitoring.

22. The Company informed the undersigned that the Law Department first learned of potential contacts between Customer Service and pharmacies on April 16, 2021, when the Director of Customer Service provided call logs to the Law Department.

23. The call logs were provided to the Law Department as part of a review of Customer Service Department contacts with physicians and the Sales Department concerning Adhansia, a Non-Opioid product. In reviewing the Customer Service calls logs, an Associate General Counsel observed that the Customer Service Department interactions included contacts with pharmacies.

24. On April 20, 2021, the Company contacted outside counsel, Skadden. While the substance of that communication, scope of the review and other issues in which Skadden may have been involved were withheld as privileged, shortly thereafter Skadden commenced its review.

25. The call logs reflected that Customer Service would affirmatively contact pharmacists, including when a patient sought to replace a product. In most instances, the calls involved assisting the patient in coordinating with the pharmacy to get a product replacement of Butrans®, or Rhodes Pharmaceuticals' generic equivalent. Butrans is an extended-release pain medicine administered through a transdermal patch, containing the opioid Buprenorphine. Each Butrans patch should be worn continuously for seven days, and the medicine is absorbed through the skin and delivered continuously for that seven-day period.

26. The caller would typically assert that: (a) the patch had fallen off or would not sufficiently adhere to their skin; (b) the patient received fewer Buprenorphine patches than they should have, due to either a missing or empty product pouch in the product box; or (c) the product was defective, in lacking adhesive or other adulteration.

27. The call would occasionally be directly received by the Customer Service Department, though more often transferred to Customer Service from another department. Most of the transferred calls came from Product Complaints but occasionally from Medical Information or other departments. Most often the inbound calls were from patients, and occasionally the calls were from a pharmacy.

28. In response to calls from patients, the Customer Service employee would contact the patient's pharmacy and ask if the pharmacy was willing to replace the Buprenorphine patch or patches for the patient. In some instances, the Customer Service employee would call the pharmacy multiple times attempting to coordinate the product replacement and credit due the pharmacy. The Customer Service employee would often then call the customer back and inform the patient whether the pharmacy agreed to replace the patch.

29. These outbound calls to pharmacies have been occurring from the time of the Injunction, and ceased before the new Standard Operating Procedure ("SOP") went into effect.

30. In those instances where the pharmacy did agree to replace the product, many of the entries in the call log note that the Customer Service employee arranged for the pharmacy to get a credit for the replaced product from the pharmacy's wholesaler.

31. While most of the Customer Service calls to pharmacies related to Buprenorphine patches, some calls placed by Customer Service to pharmacies involved attempts to replace other Opioid Products.

32. As was noted in the letter to the Monitor, and as reflected by notes provided by Skadden and directly told to the undersigned, the Director of Customer Service never considered pharmacists to be Health Care Providers, and considered the prohibitions relating to Health Care Providers to only apply to physicians.

33. Additionally, the Director of Customer Service explained that, in July 2020, two of the four members of the Customer Service team reverted to the former process of answering questions relating to active Opioid Product Savings Card programs and would provide the caller with the toll-free number for the Savings Card program, rather than referring the call to Medical Services.

34. Based on a claim of work product and attorney-client privilege, the Monitor did not review Skadden's analysis or recommendations. However, as will be discussed below, and with Skadden's input, a SOP entitled "Customer Service Department Call/Email Handling Response and Logging Process" became effective in July of 2021.

The Standard Operating Procedure

35. The SOP, implemented in July 2021, relates to both incoming and outgoing calls and emails. Regarding the outgoing communications, it provides, "In the interest of clarity, the Voluntary Injunction prohibits Customer Service from reaching out to any Patients or HCPs (including Pharmacists and thus Pharmacies) to discuss anything regarding an Opioid Product." (SOP CS 7.20, page 8, emphasis in original.)

36. The SOP defines "Health Care Professional(s)" as [a] physician, physician assistant, nurse, nurse practitioner, dentist, pharmacist, physical therapist, managed care organization representative, social worker, or student in a training program relating to an above referenced profession." (SOP CS 7.20, page 1.)

37. The SOP provides that incoming calls and emails from Patients and Health Care Professionals will be transferred to the Medical Information Department in the following situations: (i) inquiring about an existing active Opioid Product Savings Card; (ii) inquiring about financial assistance for an Opioid Product; (iii) inquiring about availability or where to find an Opioid Product; (iv) requesting an Opioid Product refund or replacement if a Product Complaint or Adverse Event has previously been filed (emphasis in original); (v) inquiring about an Opioid Product replacement if a Product Complaint or Adverse Event has previously been filed (emphasis in original); (vi) requesting a Sales Representative for an Opioid Product; and (vii) medical or general product questions such as ingredients, side effects, substitutions, etc. (SOP CS 7.20, pages 3-4.)

38. The SOP further provides that incoming calls and emails from Patients and Health Care Professionals will be transferred to the Product Monitoring Department when the communication concerns a Product Complaint, which is defined in the SOP as "[a]ny untoward

occurrence with the physical characteristics of a product or with the product's packaging, labeling, immediate container, closure, or contents." (SOP CS 7.20, page 2.)

39. The SOP also provides that incoming calls and emails from Patients and Health Care Professionals will be transferred to the Drug Safety and Pharmacovigilance Department when the communication concerns an Adverse Event, defined in the SOP as "[a]ny unwanted or unintended experience associated with the use of a drug, (prescription or over the counter (OTC)) or dietary supplement in humans, regardless of whether it is caused by the drug/supplement." (SOP CS 7.20, page 1.)

40. As to incoming calls and emails from Patients and Health Care Professionals that *can* be handled by Customer Service, the SOP permits the Customer Service Department to respond to inquiries concerning: (i) a Product Savings Card Program that does not exist or has been discontinued; (ii) Non-Opioid Product Savings Card Programs; (iii) the nonexistence of any Patient Assistance Programs; (iv) product availability or where to find a Non-Opioid Product; (v) a request for a sales representative call for a prescription Non-Opioid Product; (vi) a refund or replacement of a Non-Opioid Product; (vii) following up on the status of a prior refund request for all products, if the Product Monitoring, Drug Safety and Pharmacovigilance, or Medical Information Department had already gathered the information necessary for processing the refund request. (SOP CS 7.20, pages 4-9.)

41. Additionally, Customer Service is authorized to respond to any inquiries from direct purchasing accounts unrelated to a Product Complaint or Adverse Effect. This includes matters like purchase order tracking, missing packing slips, update on a product backorder, and various other matters.

42. The SOP also goes through the process for logging and categorizing calls received by Customer Service. (SOP CS 7.20, page 9.)

Patient, Health Care Professional or Pharmacy Prescription Drug Call Response Matrix

43. Attached to the SOP is a call-response matrix. Regarding requests for product refunds or replacements, the matrix provides that an Adverse Event/Product Complaint first be filed. Once filed, the matrix requires that calls requesting a refund or replacement of an Opioid Product be transferred from Customer Service to the Medical Information Department, unless the caller had previously requested a refund and the patient is just calling to inquire about the status of the refund check.

44. For written refund requests relating to Opioid Products, Customer Service can handle the request if no further information is needed. If a call is required to the patient or pharmacy, however, Customer Service is instructed to forward the request to the Medical Information Department.

45. Once an Adverse Event/Product Complaint is filed, Customer Service is permitted to handle all facets of refund or replacement requests relating to Non-Opioid products.

Process for Processing Requests for a Refund, Credit or Replacement

46. As part of the SOP, and attached as a separate Exhibit, the Company updated the process for processing requests for a refund, credit, or replacement.

47. Regarding refunds, it requires the caller to file an adverse event report or product complaint, then submit in writing: the reasons for the refund; full name and address; proof of payment/receipt; and the product complaint or adverse event Report ID Number.

48. It further provides that, "[g]enerally a patient/consumer Adverse Event would not be eligible or a replacement, only a refund, if requested."

49. Specific to Opioids, it provides that "[f]or a refund request due to missing Butrans patches, or a patch that has fallen off, the patient will be considered for a refund for the number of patches affected." The SOP does not address refund requests for other Opioid Products, however.

50. Regarding replacements, the policy provides that the Company will "only assist in coordinating a pharmacy replacement of a missing Purdue Butrans® or Rhodes Buprenorphine Patch(s) as a result of a packaging issue," and "[w]e do not request or assist in coordinating Pharmacy replacement of any of our other products."

51. The policy further provides, "If the patient requests replacement due to a product quality issue a phone call is made to the pharmacy to see if they are comfortable replacing the product. The patient is also required to file a Product Complaint."

52. Upon the pharmacy submitting the required documentation, a credit is issued to the wholesaler on behalf of the pharmacy for the product quantity that was replaced.

Analysis of Issues Brought to the Attention of the Monitor in the August 16, 2021 Customer Service Letter

53. In the prior Report, the undersigned noted, "The Customer Service Letter raises several matters necessitating further review and examination, including: (a) whether the actions of the Customer Service personnel are consistent with the Injunction; (b) the sufficiency of the remediation efforts the Company implemented on July 14, 2021; (c) the adequacy of the Company's training and education of its employees regarding the Injunction; and (d) whether the Company's actions in identifying, investigating, and remediating the issues raised in the Customer Service Letter prior to informing the undersigned are consistent with the letter and spirit of the Injunction's obligations that Purdue Pharma 'fully, completely and promptly cooperate with the Monitor.'" (Sixth Report, Paragraph 11.) Each will be considered in turn.

The Injunction

54. There are several provisions of the Injunction that relate to the aforementioned activities of the Customer Service Department.

55. Section II.A of the Injunction sets forth the ban on promoting Opioids or Opioid Products, providing that "[t]he Company shall not Promote Opioids or Opioid Products. . .." (Injunction, II.A.).

a. "Promote" is expressly defined in the Injunction as "the dissemination of information by the Company to a Third Party that is either likely or intended to influence prescribing practices of Health Care Providers in favor of prescribing greater amounts, quantities, doses, and/or strengths of Opioid Products." (Injunction, I.O.)

b. Moreover, "Third Party" is defined as "any person or entity other than the Company or a government entity." And "Health Care Provider" is defined as "any U.S.-based physician, nurse practitioner, physician assistant, dentist, pharmacist, podiatrist, nurse, or other person engaged in the business of providing health care services and/or prescribing an Opioid Product and any medical facility, practice, hospital, clinic, or pharmacy engaged in providing health care services and/or prescribing an Opioid Product in the United States." (Injunction, I.H.)

56. The Injunction does not preclude the Company from all contact with Health Care Providers, however. It expressly permits the Company to "[p]rovide scientific and/or medical information in response to an unsolicited request by a Health Care Provider concerning Opioid Products by providing truthful, balanced, non-misleading, non-promotional scientific or medical

information that is responsive to the specific request." (Injunction, II.2.f.) However, "[s]uch responses should be handled by medical or scientific personnel at the Company who are independent from the sales or marketing departments." (*Id.*)

57. Similarly, the Company can also interact with patients and caregivers. The Injunction provides that the Company may "[p]rovide a response to any unsolicited question or request from a patient or caregiver by (i) directing the patient or caregiver to the FDA-approved labeling and reviewing the prescribing information with the patent as relevant to their inquiry, and, to the extent the question cannot be answered solely by reference to a specific provision of the FDA-approved labeling, providing a response that is truthful, balanced, non-misleading and fully consistent with the FDA-approved labeling, if applicable; (ii) recommending that the patient or caregiver speak with a licensed Health Care Provider without naming any specific provider or healthcare institution; (iii) directing the patient or caregiver to speak with their insurance carrier regarding coverage of an Opioid Product; and/or (iv) directing the patient or caregiver to information concerning savings programs, vouchers, coupons, or rebate programs for the Company's Opioid Products." (Injunction, II.2.g.)

58. And finally, the Company must "[a]nalyze all information that the Company receives that indicates an unreasonable risk of diversion activity of a Company Opioid Product or an unreasonable potential for diversion activity of a Company Opioid Product, by a direct customer or a downstream customer, including reports by employees and customers of the Company, Health Care Providers, law enforcement, state, tribal, or federal agencies, or the media." (Injunction, II.G.1.c.).

Customer Service Contacts with Pharmacies

59. There are numerous instances where the activities of the Customer Service Department can be construed as inconsistent with the terms of the Injunction. To the extent that Customer Service's actions can be construed as inconsistent with the Injunction, the undersigned Monitor does not believe those inconsistencies were intentional.

60. As noted above, the Company is prohibited from "the dissemination of information by the Company to a Third Party that is either likely or intended to influence prescribing practices of Health Care Providers in favor of prescribing greater amounts, quantities, doses, and/or strengths of Opioid Products." Patients are Third Parties under the Injunction, and pharmacists are Health Care Providers.

61. In response to prior inquiries by patients and/or pharmacies, Customer Service Department employees directly reached out to pharmacists, requesting and/or coordinating replacement of Opioid Products. Accordingly, a strict and literal reading of the Injunction suggests that the Customer Service employees were intending to influence the prescribing practices of the pharmacist in contravention of the Injunction.

62. Moreover, other than certain circumstances not applicable here, the Company can only respond to unsolicited requests by pharmacists and other Health Care Providers. When Customer Service employees responded to calls from patients and then called pharmacies to request and/or coordinate product replacements, those calls cannot be construed as a response to an unsolicited request from a Health Care Provider.

63. Finally, "[s]uch responses [to unsolicited requests] should be handled by medical or scientific personnel at the Company who are independent from the sales or marketing Departments." (Injunction, II.2.f.) The Customer Service employees are not medical or scientific

personnel, nor are they part of or connected to departments relating to medical or scientific functions. Rather, they are part of the Commercial division, which includes the sales and marketing departments.

64. In addition to the contacts with the pharmacies, many of the Customer Service employees' interactions with patients can also be construed as inconsistent with the Injunction. The Injunction does not provide for directing patients as to how they can get a replacement Opioid from their pharmacist; arguably, at most, it permits the Customer Service employees to "recommend[] that the patient or caregiver speak with a licensed Health Care Provider without naming any specific provider or healthcare institution." (Injunction, II.2.g.). Moreover, the Customer Service Department policy effective January 2020 provided that all product complaint calls be forwarded to the Product Monitoring Department; the call logs indicated that many of those calls were taken directly by Customer Service and, when it came to coordinating a replacement product, were transferred to Customer Service from Product Monitoring.

65. Clearly, the interactions between Customer Service and pharmacies, as described above, were not directly addressed by the Injunction. Moreover, the above discussion in Paragraphs 59 through 64 presumes that the activities of the Customer Service Department are deemed "promotional" under the terms of the Injunction.

66. However, and assuming the best intentions and motivations of the patient, a request to a pharmacy to provide replacement Opioid Products isn't seeking to influence the pharmacy to provide "greater amounts, quantities, doses, and/or strengths of Opioid Products." Rather, the request and coordination are simply facilitating the replacement of Opioid Products that had already been prescribed to the patient.

67. Given the varying nature of, and justifications provided by, customers when contacting Customer Service, the policies in place since the entry of the Injunction prohibiting Customer Service from contacting Health Care Providers and requiring all product complaints to be forwarded to Product Marketing, and the continuing interest of the Company and all parties to avoid any activities that are inconsistent with the terms and spirit of the Injunction, the scrutiny and remedial actions undertaken by the Company were certainly warranted.

Savings Cards

68. Finally, in those instances when Customer Service employees provided patients with information about the active Savings Card programs, it arguable that this is promotional activity, disseminating information to a Third Party that could influence the prescribing practices of Health Care Providers. However, the Injunction permits the Company to "direct[] the patient or caregiver to information concerning savings programs, vouchers, coupons, or rebate programs for the Company's Opioid Products," and does not expressly require that the information comes from medical or scientific personnel at the Company.

69. While the undersigned does not conclude that the calls regarding savings card programs was inconsistent with the express terms of Injunction, responding to these calls was contrary to the direction provided to the Customer Service Department by the Ethics and Compliance Department and the Company's policy that had been in place since January 2020.

Practices since July 2021 and the New Standard Operating Procedure

70. The undersigned Monitor believes that, if the July 2021 Customer Service SOP is followed, the practices of the Customer Services Department discussed in this Report will be consistent with the Injunction.

71. A review of the call logs from the time the SOP went into effect through early October indicates the terms of the SOP are being followed.

72. However, the undersigned Monitor recommends the following revisions to the SOP and practices of the impacted departments of the Company.

73. **First, the Monitor recommends that the SOP and Exhibits further clarify when and how the Company will assist in replacing a Buprenorphine patch.** Exhibit 2 to the SOP provides that the Company will "only assist in coordinating a pharmacy replacement of a missing Purdue Butrans® or Rhodes Buprenorphine Patch(s) as a result of a packaging issue," and further provides, "[i]f the patient requests replacement due to a product quality issue a phone call is made to the pharmacy to see if they are comfortable replacing the product. The patient is also required to file a Product Complaint."

a. In an interview with the Monitor, however, the Director of Customer Service noted, as an example, that if a patch fell off on the second day of a seven-day cycle, the Company would allow the pharmacy to consider replacing the patch. This understanding is consistent with the call logs from the Medical Information Department reviewed by the undersigned. As the Company is arranging for a credit for the pharmacy from the Company's distributor, however, doing so is "assisting in coordinating a replacement" for reasons other than packaging issues.

b. Moreover, the SOP needs to clarify that the call to the pharmacy is made by the Medical Information Department and cannot be made by Customer Service. According to the Director of Customer Service, that is the intent and the practice since the new SOP went into effect. However, the SOP should expressly include that intent and practice.

74. **Second, the undersigned Monitor recommends that the SOP be amended to clarify under what circumstances a refund for the Company's other Opioid Products is given.** Specific to Opioids, Exhibit 3 of the SOP provides that "[f]or a refund request due to missing Butrans patches, or a patch that has fallen off, the patient will be considered for a refund for the number of patches affected." The SOP and exhibits do not address refund requests for other Opioid Products, however, and it is the understanding of the Director of Customer Service that there remains the possibility for refunds for other Opioid Products. If refunds are permitted for other Opioid Products for missing product or any other reason, this should be included in the SOP.

75. **Third, the definition of "Health Care Professional" in the SOP should be revised to capture all positions and functions covered by the definition of "Health Care Provider" in the Injunction.** While in some respects, the SOP's definition is more expansive than under the Injunction, in other respects it is not. The SOP can certainly be more expansive, but should at, minimum, cover every profession, function and entity captured in the Injunction's definition.

76. **The Company agrees to work with the Monitor to implement these revisions to the SOP.**

Adequacy of the Company's Training and Education Regarding the Injunction

77. Training of Customer Service employees concerning what is prohibited and permitted by the Injunction occurred on November 21, 2019, immediately after the Injunction went into effect, and on June 14, 2021.

78. The initial training on the Injunction consisted of individual sit-down trainings with the various impacted departments. The training was approximately one hour long.

According to the Director of Customer Service, the training was at a high level, not getting into the operational changes necessary for the Department to comply with the Injunction.

79. The materials used to train the Company's employees regarding the Injunction are uniform, without regard to the employee's position or department, although the training will spend more or less time on the various facets of the Injunction, depending on the function of the employee being trained.

80. These materials have remained consistent since November 2019, with two exceptions: first, the training materials have been updated over time to include recommendations made by the Monitor; and second, since June 2021 the training materials now expressly include the definition of Health Care Provider.

81. The training on the Customer Service Department's new SOP was much more robust. The Director of Customer Service had several meetings with the Customer Service and Medical Information employees in drafting the SOP and attachments, as well as follow up staff meetings after the SOP went into effect.

82. As earlier noted, the Director of Customer Service stated she wasn't aware that pharmacists were included in the definition of Health Care Provider. Moreover, policies set by the Ethics and Compliance Department to transfer calls relating to Savings Card programs were no longer followed by two of the four Customer Service employees six months after the initial training. Finally, the Director of Customer Service noted that the communications as to what the Customer Service Department should or should not do had been vague, and part of the confusion was that Customer Service was often told different things by the Commercial, Medical and Ethics and Compliance Departments.

83. **The undersigned has concerns about the efficacy of the training offered. Even though the general Injunction training has been updated, and an additional round of training occurred with Customer Service after the issue of contacting Health Care Providers was addressed, the Monitor recommends a more frequent and robust training schedule for all Company employees performing duties that could touch upon the prohibitions of the Injunction.**

84. **Assuming emergence from bankruptcy and the Company then conducting business under the Operating Injunction, the Monitor recommends that the Company work to establish a more interactive program to ensure that the Company's employees understand and incorporate the Operating Injunction's terms into their regular work. Because new issues can arise both in the daily business operations and through interpretation and enforcement of the Injunction, this training should occur at least every six months. The training should include not only the terms of the Injunction and Monitor recommendations, but also how the Operating Injunction impacts the operational practices of the various departments of the Company, and any changes to business practices and policies instituted to ensure conformity with the Injunction.**

85. **The Monitor has been speaking with the Company about this enhanced training, and the Company agrees to this recommendation.**

Review of Call Logs to Ensure that the Injunction is being Followed

86. The issues that arose relating to Customer Service directly contacting Health Care Providers were discovered by happenstance; had a member of the Law Department who was extremely familiar with the Injunction not been reviewing Customer Service call logs for an issue relating to one of Purdue's Non-Opioid products, neither the Company nor the Monitor

would have been made aware of the issue. Moreover, and as noted above, since July of last year, two of the members of the Customer Service team were not consistently forwarding calls relating to active Savings Card programs to Medical Information.

87. Again, the undersigned does not believe the inconsistences with the Injunction were intentional and commends the Law Department for taking immediate action upon learning of the matter. At issue, however, is if there are ways to further institutionalize safeguards or checks and balances to prevent inadvertent violations of the Injunction

88. Since July 2021, the Director of Customer Service has been frequently reviewing the Customer Service call/email logs to ensure conformity with the Injunction and the SOP. **The Monitor recommends, and the Company agrees, that these reviews will occur at least monthly.**

89. **The Monitor further recommends that a representative designated by the Company's Law Department undertake a quarterly review of the call and email logs of the Customer Service and Medical Information Departments. The purpose of the review is to identify any issues or trends that might touch on matters prohibited by the Injunction. The Company agrees to this recommendation as well.**

Review of Customer Service and Medical Information Inquires for Suspicious Ordering and Orders of Interest

90. As earlier noted, the Company must "[a]nalyze all information that the Company receives that indicates an unreasonable risk of diversion activity of a Company Opioid Product or an unreasonable potential for diversion activity of a Company Opioid Product, by a direct customer or a downstream customer, including reports by employees and customers of the Company, Health Care Providers, law enforcement, state, tribal, or federal agencies, or the media." (Injunction, II.G.1.c.)

91. The Customer Service Department is in frequent contact with the Suspicious Order Monitoring (SOM) program. For example, if an order pends or is rejected, or a customer is blocked from ordering, the Associate Director of Ethics and Compliance will contact the Director of Customer Service. Correspondingly, if a customer is ordering outside their usual cycle or other issues come to the attention of Customer Service, the Department will contact the SOM program.

92. To date, there has not been any formal process by which employees of Customer Service notify the Suspicious Order Monitoring team of information that could indicate an unreasonable risk of diversion or potential for diversion activity.

93. As part of the review of the Customer Service issue, the Director of Ethics and Compliance overseeing the SOM program reviewed the Customer Service call logs. In doing so, he identified interactions that could trigger further review or reporting. There were other instances where additional information could have been gathered to ascertain whether further action was prudent.

94. For example, in one instance, a pharmacist attempted to have Opioid Products mailed directly to the patient from the Company. Even if the pharmacist did so out of a misunderstanding or ignorance, after learning about that exchange, the Director of Ethics and Compliance notified the DEA of the request for direct mailing.

95. The SOM team's review revealed that Customer Service could benefit from guidance about what to do if a pharmacy reported that the Opioid Products it received were missing or ineffective. For example, as a result of its review of Customer Service call logs, the SOM team prepared language to remind pharmacies that they are required to report to the DEA any significant loss or shortage.

96. Another entry on the Customer Service call log revealed that a pharmacist requested a credit of 1,000 oxycodone pills, questioning the efficacy of those pills. The call was transferred from Product Complaints to Customer Service. When the Customer Service employee asked whether the pharmacy was seeking to return the pills for testing, the pharmacy stated no, because the lack of efficacy was an adverse event. Though neither a credit nor replacement was provided, the undersigned Monitor believes that the Company did not fulfill its responsibility to further review the somewhat unusual interaction.

97. Additionally, the Customer Service log revealed that there are occasions when a patient's statements might well trigger further review or reporting to DEA, including: (a) a patient reports to Customer Service that he suspects that the pharmacy has tampered with the box and shorted products, and has done so in the past; (b) a patient wanting to report a doctor who she believes over-prescribes pills; (c) a patient requesting replacement patches from customer service because of missing products, not disclosing or forgetting that she had made the same request of Customer Service several months prior.

98. The undersigned acknowledges that the Customer Service contacts with Patients and Health Care Providers that might give rise to a risk of or potential for diversion are extremely infrequent, and represent less than one percent of all the calls Customer Service receives. Moreover, under the new SOP, all interactions with Health Care Providers should be channeled through the Medical Information Department. However infrequent, the Company still has reporting obligations to the DEA and is required under the Injunction to analyze <u>all</u> information that the Company receives indicating an unreasonable risk of or potential for diversion activity.

99. **The Monitor recommends that the Ethics and Compliance/Suspicious Order Monitoring team provide training to the Customer Service and Medical Information Departments defining the types of information, communications or allegations that should be brought to the attention of the SOM team, as well as what details Customer Service should collect from the reporting Health Care Provider or patient to assist the SOM team in its review. The Company agrees to this recommendation.**

100. **The Monitor further recommends that the Director of Ethics and Compliance undertake a quarterly review of the call/email logs of the Customer Service and Medical Information Departments, to assess whether there are issues that should be reported to the SOM team. The Monitor further recommends that the Company and the undersigned will assess the value and utility of this review prior to the next report, or at a time agreed upon by the Company. The Company agrees to these recommendations as well.**

Other Considerations

101. The undersigned Monitor considered other changes in business practices to protect against potential inconsistencies with the Injunction but chose not to advance them as recommendations. These changes included: (a) removing the decision whether to provide a refund or replacement of an Opioid Product from Customer Service; (b) moving the Customer Service Department out of the Commercial Division; and (c) additional staffing for the Customer Service Department.

102. Regarding the decision to make a refund or provide a credit to the pharmacy for replacement, while Customer Service is no longer directly contacting patients or HCPs relating to product refunds or replacements, the Injunction expressly provides that responses to

unsolicited requests should be "handled by medical or scientific personnel at the Company who are independent from sale or marketing departments." However, and even though the Director of Customer Service makes the decision to refund or provide the pharmacy a credit, the undersigned Monitor concludes this is a ministerial function in signing off on the refund check or replacement. The decision whether to provide the refund or credit is made by the Product Monitoring and Drug Safety and Pharmacovigilance Departments, and not by Customer Service.

103. Regarding moving Customer Service out of the Company's Commercial division, the functions of the Customer Service Department are much more akin to business operations than sales and marketing functions. While there is at times interaction with the sales and marketing departments, I have concluded there is nothing to indicate influence by those departments over Customer Service. Considering the alignment of business purposes that Customer Services has with Pricing and Contracts and the disruption that would be caused by reorganizing, I do not recommend reorganizing the Customer Service Department by removing it from the Commercial Division.

104. Regarding additions of staff to Customer Service, the staffing has been substantially reduced through layoffs and attrition over the two decades that the Director of Customer Service has held that position, from 11 to five employees. However, the technology and business practices have also substantially changed over that same period. Moreover, the Customer Service employees have all been with the Company a substantial period and, while busy, it is not apparent that additional staffing is necessary or would add to the efficiency and effectiveness of the Customer Service Department.

Agreed Upon Process Going Forward for Issues Relating to the Injunction

105. Finally, going forward the undersigned Monitor and the Company have agreed to a protocol for when the Company becomes aware of information that may touch on potential violations of the Injunction:

1. In the event the Company learns of information that (a) directly or indirectly relates to a potential violation of the prohibitions contained in the Voluntary or Operating Injunction, or (b) the Company believes warrants a review to determine whether there has been a violation of the Voluntary or Operating Injunction, the Company shall advise the Monitor within five business days of the Law Department or Ethics and Compliance Department learning of the information.

2. To the extent the Company elects to conduct a review of the information, the Company shall promptly advise the Monitor of the initiation of the review. In addition, the Company shall respond to the Monitor's reasonable requests regarding the status of the review.

3. At the conclusion of the review, the Company shall report the results of the review and confer with the Monitor prior to making a final determination as to what, if any, remedial actions should be taken.

106. The undersigned commends the Company for undertaking this protocol. A continuing challenge of the post of Monitor is having a sufficient understanding of everything occurring in the Company, at any given time. That challenge is not unique to this particular company and monitorship appointment, but rather to the position in general. While the undersigned could certainly hire additional staff and daily be looking over the shoulder of all the business practices in any way relating to the Injunction, doing so would be inefficient and disruptive. The protocol ensures that the Monitor will become involved at the outset of potential issues relating to the Injunction that the Company identifies, rather than months after the issue has arisen.

C. Commercial Team and Pricing Arrangements

107. To gain a better understanding of the rebate, fee and discount arrangements, and the consistency of those pricing arrangements with the terms of the Injunction, the undersigned

Monitor recommended retaining consultants that could assist in undertaking a review, comparing among other things any differences in practices between scheduled and nonscheduled products, and the pricing practices of scheduled drugs across the industry. (Fifth Report, Paragraph 74.)

108. The undersigned enlisted Pearl Management Consulting ("Pearl") to assist in undertaking this review. Pearl commenced its review and analysis in late August 2021.

109. To date, Pearl has requested and received from the Company information and data relating to contracts and pricing including:

a. Organization charts, pricing committee membership, and Pricing Committee charter and procedures for Purdue and Rhodes;

b. Pricing Committee meeting agenda, meeting minutes and presentations from Purdue Pharma;

c. Standard Operating Procedures for contract operations, as well as Purdue managed care and Medicare Part D contracts, and the Commercial customer, GPO and state Medicaid supplemental program contracts for Purdue and Rhodes;

d. Pricing, sales, claims and inventory data from January 1, 2018, to March 31, 2021: WAC pricing; direct sales; indirect sales; managed care claims; Medicaid claims; and EDI 867 (inventory movement);

e. Rebate contract business models with the underlying market access and forecasting source data; and

f. Government Price Reporting Policies for Purdue and Rhodes.

110. Pearl has also had meetings with the Head of Pricing and Contracts at Purdue Pharma; Director, Government & Institutional Contract Operations at Purdue Pharma; Head of

Market Access at Purdue Pharma; Director at Purdue Pharma; Director of Analytics at Purdue Pharma and the Vice President, Sales and Marketing at Rhodes Pharmaceuticals.

111. Pearl's review and analysis includes:

a. Reviewing Company policy and standard operating procedure documentation related to pricing practices; and

b. Reviewing the structure of the Company Pricing Committee and the frameworks and analyses used by Company for scheduled and non-scheduled products when considering:

1. Wholesale Acquisition Cost ("WAC") price changes; and

2. New contractual arrangements and changes to existing contractual agreements.

c. Cataloguing Company pricing arrangements in place since January 1, 2018, identifying:

1. Net price(s) for all products included in the arrangements;

2. Formulary positioning (if applicable) of the products included in the arrangement; and

3. Requirements for customers to achieve pricing offered in the arrangement.

d. Analyzing utilization data from rebate agreements active from January 1, 2018, through March 31, 2021.

e. Reviewing the Company's government pricing policies, procedures, modeling, and calculations to identify possible scenarios that create unintended financial incentives likely to increase Opioid Product prescriptions.

f. Analyzing sales data under direct and indirect purchase agreements active from for January 1, 2018, through March 31, 2021.

112. While Pearl's review and analysis is ongoing, they have identified several recommendations and areas of further inquiry.

1. Pricing Committee Charters

113. Both Purdue and Rhodes Pharmaceuticals have pricing committee charters, setting forth the members, responsibilities, and processes guiding each company's pricing committees. These committees are responsible for overseeing and approving the Company's pricing strategies and decisions, as well as approving adjustments or deviations from those strategies and decisions for specific contracts.

114. While the charters are high-level documents, the undersigned Monitor recommends that the Company incorporate considerations of the Company's requirements under the Injunction into the charter, and thereby the committees' decisions.

115. **The undersigned recommends that the following language be incorporated into the Pricing Committee Charters:**

> **The Pricing Committee is dedicated to maintaining compliance with the pricing and contracting obligations of the Voluntary Injunction and/or Operating Injunction. The Pricing Committee is responsible for ensuring that approved pricing and contracts are not designed or intended to influence prescribing practices of Health Care Providers in favor of prescribing greater amounts, quantities, doses and/or strengths of Opioid Products.**

116. **The Company has agreed to this recommendation.**

2. Contract Terms

117. As is typical across the industry, contracts in place at Purdue and Rhodes Pharmaceuticals contain many different terms and conditions. Pearl is developing a list of contracts that may contain terms or conditions which may warrant further review and/or modification in terms of the Injunction. Pearl is also developing a list of terms and conditions that should not be included in future contracts regarding Opioid Products that can serve as a first step compliance checklist by teams responsible for contracting and the pricing committees. Furthermore, Pearl is identifying contract terms and conditions which have been negotiated by the Company that carve out Opioid Products from incentives offered to customers, to not create any incentive for the purchases of such products, which should be incorporated across all contracts. The undersigned will work with the Company once this review is completed.

3. Pricing Structure and Impact Upon Prescribing Practices

118. Many, but not all, of the Company's WAC pricing practices have remained relatively consistent since the products were launched. The Company has made changes since 2019 to its WAC pricing practices for all products to incorporate lower price increases.

119. Pearl analyzed historical and current WAC pricing for Opioid Products. In all cases, the cost per milligram of the active product decreases as the amount of active product increases. For example, the WAC price for one 80 mg tablet of OxyContin is more than 30 percent less than the WAC price of eight 10 mg tablets.

120. In conversations with Purdue Pharma, Pearl learned that since launch, the price per milligram of OxyContin decreased as the amount of active product increased. While the price of all product strengths has changed significantly over the years, decreasing cost per milligram as dosage increases has not. Prior to the injunction, non-proportional price increases

between the lower and higher strength products resulted in reducing this difference in price per milligram between the lower and higher strength opioid products, but the difference in price has remained consistent since 2018. As is generally the case with generic manufacturers, Rhodes Pharmaceuticals follows the price structure of the branded products, and reflects the decreasing cost per milligram in the generic version.

121. Other preliminary findings also deserve further consideration and analysis. For example, while the overall trend of sales has remained consistent from January 2018 to date, channel-level analysis of sales indicates that although sales to acute care facilities may be falling, sales through the 340B and Federal Supply Schedule programs appear relatively consistent.

122. The undersigned Monitor is not prepared to draw any further conclusions nor make any further recommendations until Pearl's review is complete, which will be in advance of the next Report.

II. BAN ON FUNDING/GRANTS TO THIRD PARTIES TO PROMOTE OPIOIDS

A. Spend Reports and Research Payments

123. As set forth in the last Report, in 2020 Purdue spent $16,451,000 on Medical Affairs related to the branded Opioid Products. Rhodes spent $2,826,000 in 2020 on Medical Affairs related to the Rhodes Opioid Products, and $681,000 in 2020 on research and development relating to those products. (Sixth Report, Paragraph 73.)

124. The Company had previously reported to the undersigned that there was no spending in 2020 by the Company on clinical studies involving opioids.

125. The Monitor has received and reviewed the Company's expenditures, further inquiring down to the level of individual disbursements to physicians and other Health Care Providers, and concludes that the expenditures in 2020 were either connected to Food and Drug

Administration Post Marketing Requirements, FDA Advisory Committee meetings, Risk Evaluation and Mitigation Strategy programs, or were otherwise consistent with the terms of the Injunction.

III. LOBBYING RESTRICTIONS

126. Since the filing of the Sixth Report, the Monitor has reviewed: 20 quarterly reports reflecting the actions of contracted firms at the state level and three at the federal level covering the period from July 1 through August 30, 2021; one additional report covering the second quarter of 2021; and a federal disclosure report for the activities of the Company's Director of Health Policy.

127. In only one instance did a contracted firm support a state legislative proposal; the measure related to establishing a pilot program to connect individuals in recovery with occupations through local workforce development boards.

128. In all other instances, the contracted firms only monitored legislation and legislative, executive, and administrative activities.

129. The undersigned Monitor finds that the Company is complying with Part II, Section D of the Injunction.

IV. BAN ON HIGH DOSE OPIOIDS

130. Under Section II.E of the Injunction, Purdue Pharma agreed to abide by whatever decision is made by the Food and Drug Administration (FDA) on the pending Citizens Petition dated September 1, 2017, concerning a ban on high doses of prescription and transmucosal opioids exceeding 90 morphine milligram equivalents (FDA-2017-P-5396).

131. A review of Regulations.gov finds that no action has been taken by the FDA on this Citizens Petition.

V. SUSPICIOUS ORDER MONITORING AND REPORTING

A. Schedule or Standards for Site Visits and Due Diligence and Annual Reports

132. The Company sent out requests for its customers to complete due diligence and annual review reports in early July. As of the date of this Report, all customers have submitted these reports to the Company.

133. In reviewing those reports, the Monitor noted that at least three of the customers had failed to complete the portion of the annual review report setting out the number of downstream customers. As noted in Fifth Report, this information is critical for establishing thresholds for the suspicious order monitoring process. (Fifth Report, paragraphs 151, 152, 174.)

134. In those instances, the Assistant Director of Ethics and Compliance has directly contacted the customer to get the information necessary to establish the thresholds. The Monitor finds that, even if the customer failed to include all the necessary information in submitting the annual review and due diligence reports, the Company has been diligent in follow up with the customer, thereby receiving the necessary information.

135. As to the frequency and regularity of the site visits, in addition to the site visit occurring in onboarding a new customer, the Company is now visiting each customer at least once every three years and has updated its SOP to reflect these changes.

136. As was noted in the last report, 18 of 56 customers had not been visited at least three years. (Sixth Report, paragraph 158.) Accordingly, Ethics and Compliance has been undertaking these site visits of existing customers, and all 18 are scheduled to be completed by December 8, 2021. To date, all site visits continue to be virtual.

137. The Monitor finds that Ethics and Compliance is fulfilling the recommendations of the last Report in terms of site visits and updating the SOP and commends the SOM team for promptly doing so. (Sixth Report, Paragraph 161.)

B. Independent Corroboration of Customer's Justifications for Pended Orders

138. In the Sixth Report, the undersigned reviewed the corroboration provided by customers for a sample of pended orders that were released by the Company and recommended that the Company continue to find avenues to ensure that every order that is released based on a customer's representations has some degree of corroboration attached to that released order. (Sixth Report, Paragraphs 162-168).

139. The Monitor has reviewed the monthly SOM reports and interviewed members of the Ethics and Compliance Department responsible for Suspicious Order Monitoring.

140. Ethics and Compliance is continuing to find independent sources to corroborate customer justifications for increased ordering. Over the past quarter they have been receiving weekly customized reports from the Company's marketing department showing, among other things, the market share of all manufacturers of Opioid Products that are also manufactured by the Company. This information provides insight into changes in ordering due to supply chain disruptions from other manufacturers.

141. Additionally, the Company now has access to Amerisource Bergen's CERTIO® program (https://vimeo.com/amerisourcebergen/review/472627988/445d588777), and is also receiving weekly reports from Amerisource Bergen. This information includes, among other things, the "days on hand" supply of the Company's products at each Amerisource Bergen distribution center, as well as orders from Amerisource Bergen's primary downstream customers for the Company's Opioid Products fulfilled through those individual distribution centers. This

information can help verify or corroborate the information provided in response to inquiries about pended orders.

142. It is noteworthy that Amerisource Bergen is the only one of the three largest distributors to provide this level of detailed information to manufacturers. As noted in the Fifth Report, 97 percent of Purdue's sales and 96 percent of Rhodes Pharmaceuticals' sales occurred through three distributors: Amerisource Bergen, Cardinal and McKesson. (Fifth Report, paragraph 43.) The undersigned Monitor encourages the Company to keep requesting similar information of the other principal distributors, and hopes those distributors will take notice of this Report.

143. It is also noteworthy that the Company does not ever rely on just outside sources in releasing pended orders, and in each instance reaches out directly to the distributor/customer. If the customer fails to timely respond, or the response is deemed insufficient, Purdue Pharma rejects the order. This direct exchange can also assist the customer, such as in instances where the customer's demand planning software isn't adequately capturing market or supply conditions.

C. Review of Downstream Customers

144. In the prior Report, the undersigned detailed additional steps that the Company had been taking to better identify downstream orders and customers of interest, and recommended that the Company continue to work with its outside vendor as well as other data sources to further explore measures that can more effectively identify these orders and customers, including whether sales and inventory data can more effectively and timely assist in identifying orders and customers of interest than the analysis of chargeback data. (Fifth Report, paragraphs 170-181.)

145. Since the last report, the Company has worked with its vendor to further enhance the Due Diligence Plus program to enhance the sales information by location and monthly changes in downstream customers.

146. The Company is also receiving weekly detailed sales reporting information, or reports containing "867 data," from Amerisource Bergen regarding the Company's generic products. By reviewing this information, the Company identified five unique downstream customer orders of interest for further review and reporting. Again, Amerisource Bergen is the only one of the top three distributors providing this level of detailed information to the Company.

147. Accordingly, the Company is further incorporating 867 data in its review of downstream customers, while still also reviewing the chargeback information. The undersigned commends the Company in exploring other avenues and data sources in doing so.

D. Reporting of Downstream Orders of Interest or Customers of Interest to the Distributor and Drug Enforcement Administration

148. As discussed in the prior Report, beginning in July 2021, the Company began reporting all reportable downstream customer's orders of interest, both to the customer's distributor/parent and to the DEA. (Fifth Report, Paragraphs 182-195.)

149. Between August 1 and October 31, 2021, the Company has reported 35 downstream orders of interest to the DEA and the downstream customer's distributor. As noted above, five of those orders of interest were identified through using 867 data.

150. In response to those reports, the DEA has frequently contacted the Company requesting additional information. Many of the distributors have responded as well. Based on these inquiries and responses, the Director of Ethics and Compliance does not have concerns that the increased reporting is overburdensome to the DEA, and the reporting of all downstream customer orders of interest will continue.

VI. INITIAL COVERED SACKLER PERSONS

151. The undersigned has received signed certifications from the Initial Covered Sackler Persons or their representatives certifying that they have not actively engaged in the opioid business in the United States and have taken no action to interfere with Purdue Pharma's compliance with the Injunction.

VII. MISCELLANEOUS

152. It is possible that this will be the final Monitor Report under the Injunction. On the Effective Date of the Plan of Reorganization, the NewCo Operating Injunction takes effect, as does the NewCo Operating Agreement and the NewCo Governance Covenants.

153. There are substantive and procedural differences between the injunctions. In the upcoming months, the undersigned will assess and evaluate those differences, as well as determine whether a final Report under this extant Injunction is warranted.

The Undersigned Monitor respectfully submits this Seventh Report with the observations and recommendations contained herein.

STEPHEN C. BULLOCK
Monitor